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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,022	09/12/2000	Antonio Lopez Cabrera	U-012473-1	5837

7590 04/23/2003

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/23/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.		Applicant(s)	
	09/660,022		CABRERA ET AL.	
	Examiner		Art Unit	
	Todd D Ware		1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Receipt amendment filed 1-29-03 is acknowledged. Claims 21-23, and 25 have been amended as requested. Claims 2-25 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 1-29-03 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 2-21, 25 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sachs et al (5,945,124; hereafter '124).

Art Unit: 1615

'124 discloses pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims). The release-slowing layer comprises ethylcellulose and HPMC.

4. Claims 2-21, 25 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sachs et al (5,945,124; hereafter '124) or Sachs et al (6,068,856; hereafter '856).

'124 and '856 disclose pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-21, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al (5,945,124; hereafter '124) or Sachs et al (6,068,856; hereafter '856).

'124 teaches pantoprazole pellets having a core, a layer comprising HPMC and pantoprazole, another layer that is a release-slowing layer applied over the

Art Unit: 1615

HPMC/pantoprazole layer, and an enteric coating applied thereon (abstract; C 3, L 61-C4, 14; C4, L 20-23; C 4, L 48-C 6, L 9; example 3; claims). The release-slowing layer comprises ethylcellulose and HPMC. Plasticizers and other excipients are also contemplated. Furthermore, varying the thickness (therefore the amount) controls the release rate. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to provide mixtures of pellets having different release profiles in an effort to provide quicker release of the active agent while also providing prolonged release of the active agent.

7. Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachs et al (5,945,124; hereafter '124) in view of Paradissis et al (5,445,829; hereafter '829) or Sachs et al (6,068,856; hereafter '856) in view of Paradissis et al (5,445,829; hereafter '829).

'124 and '856 are relied upon for all that they teach as stated previously. Neither '124 nor '856 teaches the limitation where the pellets have different release profiles of the active agents.

'829 is relied upon for teaching capsules comprising fast and slow release layered pellets to provide both a quicker onset of action and a prolonged duration of action.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '829 with '124 or '856 with the expectation of

Art Unit: 1615

providing a particular dose release profile that provides both a quick onset of action and a prolonged duration of action.

Response to Arguments

8. Applicant's arguments filed 1-29-03 have been fully considered but they are not persuasive. Since applicants' arguments are based upon the same principle, the response to arguments is applied concurrently for the responses to the different rejections.

9. Applicant argues that amendment of claim 25, section b, to require that the layer over the inert nucleus (a) consists of an acid labile benzimidazole compound, an inert, non-alkaline polymer soluble in water and one or more pharmaceutically acceptable inert excipients overcomes the prior art, since the sodium hydroxide of the prior art is not required in the present invention. However, this argument is not found persuasive. Section b includes one or more pharmaceutically acceptable inert excipients and sodium hydroxide is within this limitation, since the specification defines "inert" as not reacting with the active ingredient. It is also the position of the Examiner that the prior art teaches omission of the sodium hydroxide in column 4, lines 20-31 of '124 and '856. At these locations, the references teach that the sodium hydroxide is added only to increase the buffering capacity if this is so desired. It does not teach that it is required. Accordingly, the rejection is maintained.

Conclusion

Art Unit: 1615

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
April 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600